# DEVICES AND METHODS FOR OVERFILLING DRUG CONTAINERS

## FIELD OF THE DISCLOSURE

**[0001]** Various embodiments of the present disclosure relate to devices and methods for overfilling primary packaging components. More specifically, particular embodiments of the present disclosure relate to devices and methods for overfilling syringes, including prefillable syringes.

## INTRODUCTION

**[0002]** Primary packaging components, such as syringes, intravenous fluid containers, vials, and other drug containers, are specified to hold a maximum volume of formulated drug product or other fluid. For example, a syringe may be manufactured and sold with a nominal volume, or a maximum volume that the syringe has been tested to hold while still ensuring proper functioning of the syringe's stopper, plunger, and other parts, without compromising the contents or integrity of the stoppered syringe. In particular, a nominal volume of a prefillable syringe may be specified so as to ensure that the syringe, once filled, retains its integrity through various post-filling processes, such as packaging and shipment. In some situations, however, the nominal volume of a primary packaging component may be less than a desired volume of formulated drug substance for inclusion in the primary packaging component, due to, for example, a disparity between the nominal volume of the packaging and a desired dosage volume, or a lack of suitable larger packaging.

## SUMMARY

**[0003]** The present disclosure relates to drug products, and methods of their preparation. In particular, the present disclosure relates to overfilling primary packaging components with formulated drug substances.

**[0004]** In an aspect of the present disclosure, there is provided a method of preparing a drug product, comprising introducing a volume of a formulated drug substance into a primary packaging component, wherein the volume of the formulated drug substance is greater than a nominal volume of the primary packaging component, and positioning a stopper within the primary packaging component, wherein positioning the stopper comprises applying a vacuum to the stopper.

**[0005]** In an embodiment, the primary packaging component is a syringe. In a further embodiment, the primary packaging component is a prefillable syringe. In a further embodiment, the primary packaging component is a prefillable syringe having a nominal volume of at least 1 mL. In yet another embodiment, the primary packaging component is a prefillable syringe, the nominal volume is 1 mL, and positioning the stopper within the primary packaging component includes inserting the stopper into a body of the syringe such that an end of the stopper closest to a flange of the syringe is between about 2.5 mm and about 5.0 mm away from the flange of the syringe. In another embodiment, applying the vacuum to the part of the primary packaging component includes subjecting the part of the primary packaging component to a pressure of between 70 and 75 mBar.

**[0006]** In one embodiment, the volume of the formulated drug substance is between 1.05 mL and 1.30 mL. In a further embodiment, the volume of the formulated drug substance is between about 110% and about 140% of the nominal volume of the primary packaging component. In another embodiment, the formulated drug substance is at least 0.05 mL greater than the nominal volume of the primary packaging component. In a further embodiment, the formulated drug substance comprises one of a protein, a nucleic acid, or a gene therapy medicament. In yet another embodiment, the formulated drug substance comprises an antibody and at least one excipient. In another embodiment, the formulated drug substance comprises an antibody solution, wherein the antibody is present in the solution at a concentration of at least 100 mg/mL. In a further embodiment, the formulated drug substances comprises an antibody, and has a viscosity of at least 5 cPoise.

**[0007]** In one embodiment, the method includes placing the primary packaging component into additional packaging. In another embodiment, the method may be repeated for each of a plurality of primary packaging components in a batch. For example, a batch of primary packaging components may comprise 80 prefilled syringes.

**[0008]** In a further aspect of the present disclosure, a drug product is prepared by one of the above-described methods.

**[0009]** In another aspect of the present disclosure, there is provided a method of preparing a drug product, comprising introducing a volume of a formulated drug substance into a prefillable syringe, the formulated drug substance comprising an antibody, wherein the volume of the formulated drug substance is greater than a nominal volume of the prefillable syringe, and stoppering the prefillable syringe using one of a vacuum stoppering process or a vacuum-assisted stoppering process.

**[0010]** In another aspect, there is provided a drug product, comprising a primary packaging component having a nominal volume, a volume of formulated drug substance in the primary packaging component, wherein the volume of formulated drug substance is greater than the nominal volume, and a stopper. In an embodiment of this aspect, the primary packaging component is a prefillable syringe. In a further embodiment, the prefillable syringe has a body and a flange surrounding an opening in the body, and a minimum distance between the flange and the stopper is at least 2.5 mm. In yet another embodiment, the nominal volume is 1 mL, and the volume of formulated drug substance is at least 1.05 mL. In another embodiment, the formulated drug substance comprises a protein, a nucleic acid, a blood component, a vaccine, an anti-allergenic, a gene therapy medicament, an antibiotic, a pain management medication, an anesthetic, and/or a hormone. In a further embodiment, the formulated drug substance comprises an antibody.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0011]** The accompanying drawings, which are incorporated into and constitute a part of this specification, illustrate various exemplary embodiments and, together with the description, serve to explain the principles of the disclosed embodiments. The drawings show different aspects of the present disclosure and, where appropriate, reference numerals illustrating like structures, components, materials and/or elements in different figures are labeled similarly. It is understood that various combinations of the structures, components, and/or elements, other than those specifically shown, are contemplated and are within the scope of the present disclosure.